

DOCKET NO.: JJPR-0027/ORT-1462

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Loretta Itri, et al.**

**Application No.: 09/921,516**

**Filing Date: August 1, 2001**

**For: IMPROVED ANTI-VIRAL AND ANTI-TUMOR CHEMOTHERAPY BY  
ADMINISTRATION OF ERYTHROPOIETIN**

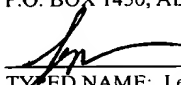
**Confirmation No.: 6089**

**Group Art Unit: 1642**

**Examiner: Canella, Karen A.**

DATE OF DEPOSIT: March 21, 2005

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Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☒ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☒ Copies of reference numbers **73 thru 91** listed on the attached Form PTO-1449 are enclosed herewith.

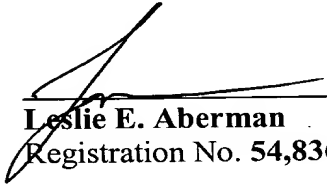
- ☐ Copies of reference numbers - on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: **March 21, 2005**



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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. <b>JJPR-0027/ORT-1462</b>	Application No. <b>09/921,516</b>
	Applicant <b>Loretta Itri, et al.</b>	
	Filing Date <b>August 1, 2001</b>	Group <b>1642</b>
	Confirmation No. <b>6089</b>	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

73	Camma, C. et al., "The Effect of Interferon on the Liver in Chronic Hepatitis C : A Quantitative Evaluation of Histology by Meta-Analysis", <i>Journal of Hepatology</i> , <b>1997</b> , 26, 1187-1199
74	Demetri, G.D. et al., "Quality-of-Life Benefit in Chemotherapy Patients Treated with Epoetin Alfa is Independent of Disease Response or Tumor Type: Results from a Prospective Community Oncology Study", <i>Journal of Clinical Oncology</i> , <b>1998</b> , 16(10), 3412-3425
75	Kakizaki, S. et al., "Evaluation of Twice-Daily Administration of Interferon- $\beta$ for Chronic Hepatitis C", <i>journal of Viral Hepatitis</i> , <b>1999</b> , 6, 315-319
76	Lavezzo, B. et al., "Treatment of Recurrent Hepatitis C in Liver Transplants: Efficacy of a Six Versus a Twelve Month Course of Interferon alfa 2b with Ribavirin", <i>Journal of Hepatology</i> , <b>2002</b> , 37, 247-252
77	Maddrey, W.C. Md., "Safety of Combination Interferon alfa-2b/Ribavirin Therapy in Chronic Hepatitis C-Relapsed and Treatment-Naive Patients", <i>Seminars in Liver Disease</i> , <b>1999</b> , 19(1), 67-75
78	Miles, S.A., "The Use of Hematopoietic Growth Factors in HIV Infection and Aids-Related Malignancies Cancer Investigation", <b>1991</b> , 9(2), 229-238
79	Poynard, T. et al., "Randomised Trial of Interferon $\alpha$ 2b Plus Ribavirin for 48 Weeks or for 24 Weeks Versus Interferon $\alpha$ 2b Plus Placebo for 48 Weeks for Treatment of Chronic Infection with Hepatitis C Virus", <i>The Lancet</i> , <b>1998</b> , 352, 1426-1432
80	Weisz, K.B. et al., "Erythropoietin Use for Ribavirin/Interferon Induced Anemia in Patients with Hepatitis C", <i>Hepatology</i> , <b>October 1998</b> , 28(4), 288A, XP009031718
81	Wolchok, J. et al., "Prophylactic Recombinant Epoetin Alfa Markedly Reduces the Need for Blood Transfusion in Patients with Metastatic Melanoma Treated with Biochemotherapy", <i>Cytokines Cellular and Molecular Therapy</i> , <b>December 1999</b> , 5(4), 205-206
82	Interaction between $\alpha$ -Interferon and Erythropoietin in Antiviral and Antineoplastic Therapy in Uraemic Patients on Haemodialysis", <i>Nephron Dial. Transplant</i> , <b>1993</b> , 8(11), 1308



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	Filing Date <b>August 1, 2001</b>	Group <b>1642</b>
	Confirmation No. <b>6089</b>	

**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	83	6,172,046 B1	01/09/01	Albrecht	514	43
	84	6,268,336 B1	07/31/01	Niitsu, et al.	514	8
	85	6,299,872 B1	10/09/01	Albrecht, et al.	424	85.7
	86	6,387,365 B1	05/14/02	Albrecht, et al.	424	85.4
	87	6,403,564 B1	06/11/02	Ganguly, et al.	514	43
	88	6,461,605 B1	10/08/02	Cutler, et al.	424	85.7
	89	6,472,373 B1	10/29/02	Albrecht	514	43
	90	6,673,775 B2	01/06/04	Ganguly, et al.	514	43

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	91	WO 98/19670	05/14/98	PCT		

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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